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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/592,680	06/12/2000	Steven Schraga	P19570	4446

7055 7590 09/09/2004

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EXAMINER	
BUI, VY Q	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/592,680	SCHRAGA, STEVEN	
	Examiner	Art Unit	
	Vy Q. Bui	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-28 and 33-127* is/are pending in the application.

4a) Of the above claim(s) *23-28* is/are withdrawn from consideration.

5)☒ Claim(s) *52-68* is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☒ Claim(s) *See Continuation Sheet* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11/6/2000.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 20,34-39,41,43-45,47,48,69-76,78,80-82,84,85,89-96,98,100-102,104,105,109-114,118,119,121,123 and 124.
Continuation of Disposition of Claims: Claims objected to are 21,22,33,40,42,46,49-51,77,79,83,86-88,97,99,103,106-108,115-117,120,122 and 125-127.

DETAILED ACTION

Election/Restrictions

The Applicant elected with traverse the species as shown in Fig. 16 for further examination. Claims 23-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species as shown in Figs. 15 and 17, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/20/2004.

Further examination of non-elected species would cause more issues and cause a serious burden for this case with many claims for consideration. However, if an amended generic claim is allowed, the dependent claim(s) related to the non-elected species will be allowed as well.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

At least claims 20, 34, 52, 69, 89 and 109 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 11, 24, 31 and 41 of U.S. Patent No. 6,156,051. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim the same invention substantially having the same main structural limitations such as a housing, a cover/cap, a lancet/needle holding member, a trigger, a biasing member, a penetration depth adjustment mechanism including a stop within a housing and a protrusion on the lancet/needle holding member.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Line 2 of claim 21 recites the limitation "the alignment mechanism". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 20, 34-39, 41, 43-45, 47-48, 69-76, 78, 80-82, 84-85, 89-96, 98, 100-102, 104-105, 109-114, 118-119, 121 and 123-124 are rejected under 35 U.S.C. 102(e) as being anticipated by DAVIS et al (5,984,940).

As to claims 20, 34-39, 41, 43-45, 47-48, 69-76, 78, 80-82, 84-85, 89-96, 98, 100-102, 104-105, 109-114, 118-119, 121 and 123-124, DAVIS-'940 (Figs. 1-24; col. 9, lines 45- col. 12, line 34) discloses housing 42/38, cam surface 158 as a stop/a protrusion contained within housing 42, cap/cover48, lancet/needle holding member 142 having protrusion 164 and slot 172, biasing element 96, additional biasing member 118, trigger/button 44 an depth adjustment mechanism including stop 158, protrusion 164 of lancet/needle holding member 142, adjustment screw/closure 114 (which partially closes distal opening of housing 42/38, rod 78, blade 82, end cap 34 with indicia (col. 9, lines 41-44) as recited in the claims.

Allowable Subject Matter

Claims 52-68 are allowed.

Claims 21-22, 33, 40, 42, 46, 49-51, 77, 79, 83, 86-88, 97, 99, 103, 106-108, 115-117, 120,122,125-127 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T Nguyen can be reached on 703-308-2158. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

04/03/2004

Vy Q. Bui
Primary Examiner
Art Unit 3731